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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,742	10/06/2005	Deborah Addison	JJM0620USPCT	3713
27777	7590	12/13/2007		
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER JACKSON, BRANDON LEE	
			ART UNIT	PAPER NUMBER
			3772	
			MAIL DATE	DELIVERY MODE
			12/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,742

Applicant(s)

ADDISON ET AL.

Examiner

Brandon Jackson

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 5-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to amendments/arguments filed 11/13/2007. Currently claims 1-2 and 5-15 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/2007 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-2 and 5-15 have been considered but are moot in view of the new ground(s) of rejection. However, Applicant has failed to sufficiently provide evidence common ownership of Kirwood et al. (US Patent Application Publication 2004/0241214) in accordance with MPEP 706.02(I).

Claim Objections

Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

dependent form, or rewrite the claim(s) in independent form. Claim 15 provides no further limitation of claim 1, it merely reclaims the same limitations of claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the

broad recitation "at least one aperture", and the claim also recites "only one aperture" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 and 5-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirkwood et al. (U.S. Patent Application Publication 2004/0241214) in view of Heinecke (US Patent 4,499,896). Kirkwood discloses a wound treatment device (1) comprising a water-impermeable (par 0058) envelope (par 0061) made of a flexible sheet (par 0013 and 0015) having at least one aperture (par 0011) that is blocked by a degradable material (par 0014) that breaks down in the presence of exudates (par 0014) thereby permitting therapeutic substances to pass through the apertures to the

wound (par 0011). The total area of the apertures is from about 0.01 to 1 cm² (par 0018). The degradable material comprises a substrate for an enzyme present in wound fluid (par 0014). The degradable material comprises a material from the group of polylactide/polyglycolide copolymers, oxidized regenerated cellulose, and mixtures thereof (par 0024). Suitable therapeutic substances include antiseptics such as silver sulfadiazine, chlorhexidine, analgesics, steroids, antibiotics, growth factor, or mixtures thereof (par 0023). The device (1) provides sustained release of therapeutic agent into the wound fluid following the opening of the aperture (par 0048). The therapeutic substance is dispersed in or on a solid substrate (par 0011). The therapeutic substance is dispersed or encapsulated in a bioerodible substance (par 0048) selected from a group comprising proteins, polysaccharides, biodegradable synthetic polymers, glycosaminoglycans and mixtures thereof (par 048). The wound treatment device is packaged in a sterile microorganism-impermeable container (par 0062). Kirkwood fails to disclose the envelope having only one aperture. However, Heinecke discloses a wound treatment device (15) comprising a water impermeable (cols. 5-6, lines 60-7) envelope (19) having one aperture (18) in the envelope (19). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Kirkwood device to have only one aperture in the envelope, as taught by Heinecke, in order to force all the wound exudate into the wound dressing.

The applied reference has common inventors Breda Cullen and Derek Silock with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C.

102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinecke (US Patent 4,499,896) in view of Arnold (U.S. Patent 5,759,570). Heinecke discloses a wound treatment device (15) comprising a water impermeable (cols. 5-6, lines 60-7) envelope (19) having one aperture (18) in the envelope (19), wherein the aperture is between .01 and 1 sq-cm (col. 10, lines 31-32). The envelope (19) is formed of flexible sheet material because it has to expand and contract with the amount of fluid in the envelope (19). Heinecke fails to disclose a degradable material blocking the apertures, a therapeutic agent behind the degradable material and dispersed in a bioerodile substance, and a microorganism-impermeable container. Arnold discloses a wound dressing (1) comprising a water-impermeable envelope (col. 3, lines 49-54). The envelope contains a slow release therapeutic substance (col. 5, lines 4-6) that is released in the presence of wound fluid (col. 4, lines 22-25). The layer containing the therapeutic substance, dispersed on the wound contact layer, is degradable or bio-absorbable and contains collagen and glycosaminoglycans (col. 4, lines 52-53), which also provides a substrate for the enzymes to act upon. The wound dressing (1) also contains microbioside, such as chlorhexidine and maintains a sterile environment for the wound (col. 4, lines 10-14). The wound dressing (1) container is impermeable to microorganisms (col. 3, lines 58-60). Therefore it would be obvious to one of ordinary skill in

the art at the time of the invention to modify the Heinecke device to have therapeutic agent and degradable material blocking the aperture, as taught by Arnold, in order to allow therapeutic agent to be released into the wound, which aids in the rapid healthy healing of the wound.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon Jackson whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

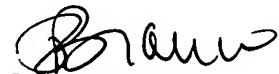
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 12/10/07
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Examiner
Art Unit 3772

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